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Applicant's or agent's file reference <b>M915-PCT</b>	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. <b>PCT/JP 03/13954</b>	International filing date (day/month/year) <b>30.10.2003</b>	Priority date (day/month/year) <b>30.10.2002</b>
International Patent Classification (IPC) or national classification and IPC Int.Cl. <sup>7</sup> <b>A61K39/00, A61K35/12, A61K38/17, A61K48/00, A61P35/00</b>		
Applicant <b>CHUGAI SEIYAKU KABUSHIKI KAISHA</b>		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of \_\_\_\_\_ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand <b>27.11.2003</b>	Date of completion of this report <b>24.09.2004</b>		
Name and mailing address of the IPEA/JP <b>Japan Patent Office</b> 3-4-3, Kasumigaseki, Chiyoda-ku, Tokyo 100-8915, Japan	Authorized officer <b>MOTOHIRO OKUBO</b>	4C	8828
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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP 03/13954

**I Basis of the report****1. With regard to the elements of the international application:\***

- ☒ the international application as originally filed
- ☐ the description:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the claims:  
Nos. \_\_\_\_\_, as originally filed  
Nos. \_\_\_\_\_, as amended (together with any statement) under Article 19  
Nos. \_\_\_\_\_, filed with the demand  
Nos. \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the drawings:  
sheets/figs \_\_\_\_\_, as originally filed  
sheets/figs \_\_\_\_\_, filed with the demand  
sheets/figs \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**

- ☒ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

**4. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_

**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	1-12	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-12	NO
Industrial applicability (IA)	Claims	1-12	YES
	Claims		NO

**2. Citations and explanations (Rule 70.7)**

• D 1 : TREON, et al. Immunotherapeutic strategies for the treatment of plasma cell malignancies. Seminars in Oncology, 2000, vol.27, no.5, p.598-613  
see the whole document, especially  
line 47, right column, page 601 to line 12, left column, page 602 ;  
lines 4-36, left column, page 604 ;  
line 10-36, left column, page 605

• D 2 : WO 01/77362 A1 (CHUGAI SEIYAKU KK) 2001.10.18  
see the whole document, especially  
claims ;  
lines 1-21, page 4 ;  
line 11, page 27 to line 24, page 33 ;  
line 8, page 43 to line 11, page 51 ;  
Registry No. 165944-11-6, 239789-24-3, 368511-79-9, 368511-80-2, 368511-81-3  
& AU 2001/46846 B

None of the subject matter of claims 1-12 involves an inventive step either over D1 or over D1 and D2.

D1 discloses immunotherapeutic strategies including the following methods (1) to (3) for the treatment of plasma cell malignancies such as multiple myeloma (MM) :

- (1) immunization with functional dendritic cells pulsed with a tumor antigen or DNA encoding a target tumor antigen (see [page 604, left column, line 4-36]) ,
- (2) immunization directly with an target tumor antigen e.g. MM-ideotypic protein (see [page 604, left column, line 38 - page 605, left column, line 8]) ,
- (3) immunization with DNA plasmids encoding a target tumor antigen (see [page 605, left column, line 10-36]) .

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: V.

D1 does not concretely describe HM1.24 for the use as a target antigen for the above disclosed treatment of MM, however, D1 implies that HM1.24 would be one of the typical candidates as a target for antibody-mediated therapy of MM (see [page 599, left column, line 3 or page 601, right column, line 47 - page 602, left column, line 12] ). Therefore, taking into consideration the above-mentioned implication, a person skilled in the art would easily employ either HM1.24 as a target antigen or HM1.24-encoding gene ( e.g. DNAs disclosed in D2 ) as a gene thereof.